UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,089	08/21/2003	David Ernest Hartley	PA-5340 -RFB	7302

9896 7590 07/20/2006

COOK GROUP PATENT OFFICE
P.O. BOX 2269
BLOOMINGTON, IN 47402

EXAMINER	
ROGERS, KRISTIN D	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,089	HARTLEY ET AL.	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9,11,12,14,28 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 1 paragraph 4, filed April 27, 2006, with respect to the title have been fully considered and are persuasive. The objection of the title has been withdrawn. The Examiner acknowledges the amended title: VARIABLE STIFFNESS ATRAUMATIC GUIDE WIRE.

2. Applicant's arguments filed April 27, 2006 have been fully considered but they are not persuasive. The objection regarding claimed subject matter entitled to the priority date of 60405161 is not withdrawn. The Examiner notes that the claimed subject matter particularly the dimensions of the proximal zone, the radius of curvature of the distal curve and tip zone is not disclosed within the priority document. The claimed limitations of the structural dimensions of the guidewire of the currently amended claim 1 are entitled to the priority date of the filing of the Application 10645089, August 21, 2003. The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60405161, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Accordingly, claims 1,3-4,7-9,11-12,14,28, and 35 are not entitled to the benefit of the prior application.

3. The Examiner acknowledges cancellation of claims 2,5-6,10,13,15-27, and 29-34.

4. Applicant's arguments with respect to claims 1,3,4,7,8,9,14,28 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1,4,8,9,12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al. (5421349) in view of Lafontaine (5662621), in further view of Worley et al. (20030208141). In regard to claims 1,4,8,9,12 and 14, Rodriguez et al. shows a guidewire for a medical device comprising an elongate central zone comprising of mandrel 11 of high stiffness (column 3, lines 62-63), tapered mandrel proximal zone of transition from high to semi-stiffness 20 (column 2, lines 7-11) consisting of a length of 2 inches or 5 cm (claim 1), and tapered distal zone of transition from high stiffness to flexible 14 (column 2, lines 66-68). The distal end 14 further comprises a pre-formed bend adjacent the distal end formed in a part circular shape having a length of 3 inches (See Fig.1 and claim 1) at the proximal end (column 2, lines 36-37 Fig. 2). Rodriguez further shows a tapered mandrel proximal zone 20 with coil 30 extending its length, the coil being of substantially constant diameter (column 3, lines 26-29) formed into a rounded tip 32 (Figure 2) and a tapered mandrel portion of distal zone 14 of constant reduced diameter 16 with coil 18 along the tapered distal mandrel

of constant reduced diameter 16. Distal coil 18 is of substantially constant (column 2, lines 19-20) diameter terminating in a rounded tip (Figure 1). Rodriguez et al. lacks disclosure regarding the structural dimensions of the guidewire distal zone radius of curvature and tip zone radius of curvature. Lafontaine teaches a guidewire for a medical device including a distal zone 22 comprising of three zones: Zone 1 semi-stiff adjacent central zone 24, Zone 2 transition zone, and Zone 3 of high flexibility. Lafontaine includes heating coils 60,62,64 for heating the zones respectively, thus varying the stiffness of the zones (Figures 2 and 3, column 3 and column 6 lines 3-26). It is an inherent property that the heating of the transition zones alters the flexibility or stiffness of the guidewire (column 3 lines 22-27 and lines 48-59). Lafontaine lacks disclosure of the radius of curvature of the distal zone and the tip zone. Worley et al. teaches a guidewire for a medical device with distal zone having a radius of curvature of 6-18 cm that comprises a portion of the central zone, semi-stiff zone, and transition zone; and further comprising a tip zone of high flexibility 20 and 22 having a radius of curvature of 1.2 to 11.5cm or 12.7 to 114.3 mm (Figure 2, paragraph 42,43,47,48 and 63) for introducing the guidewire without damaging surrounding tissue. The Examiner notes that the specification provides no criticality of the claimed ranges cited in claim 1. Therefore it would be obvious to one having ordinary skill in the art at the time of the invention to modify Rodriguez et al. with a distal zone comprised of three zones of transition as taught by Lafontaine and a distal zone and tip zone having a radius of curvature in the range of 5 to 15 cm and 5 to 20 mm respectively, as taught by Worley et al. since such modification would provide a guidewire that is atraumatic to the

vasculature. (Connors et al. 20040039304 paragraph 15 discloses the claimed radius of curvature of the distal zone.)

9. Claims 3, 28, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al., Lafontaine, and Worley et al. as applied to claim 1 above, and further in view of Cornelius et al. (5924998). Rodriguez et al. shows a guidewire for a medical device including a proximal, central, and distal zone with a polytetrafluoroethylene coating. Rodriguez et al. lacks disclosure of the central zone comprising a stainless steel mandrel, proximal and distal coils being covered in polytetrafluoroethylene, and portions of the guidewire being radiopaque. Cornelius et al. teaches a guidewire comprising a central zone containing a stainless steel mandrel 28 (column 3 lines 28-30) coil 42 formed of stainless steel coated in polytetrafluoroethylene (PTFE) (column 4, lines 10-12) and a radiopaque distal tip 38 (column 3, lines 42-43) for making the coil hydrophobic and X-ray detectable. Therefore it would have been obvious to one having ordinary skill in the art to modify Rodiriguez et al. with a stainless steel mandrel, proximal and distal coils coated in PTFE and a radiopaque distal tip as taught by Cornelius et al. since such modification would provide a hydrophobic X-ray detectable guidewire.

10. Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez et al., Lafontaine, and Worley et al. as applied to claim 1 above, and further in view of Erickson et al. (566458). Rodriguez et al. shows a guidewire for a medical device comprising proximal and distal zone wire coils 30 and 18 wherein the wire coils are epoxied or soldered to the proximal and distal mandrel (column 3, line 45).

Rodriguez et al. lacks wire coils that are laser welded to the proximal and distal zone. In regard to claims 7 and 11, Erickson et al. teaches a guidewire for a medical device comprising proximal wire coil 22 and distal wire coil 24 attached to proximal and distal mandrel by laser spot-welding (column 6, lines 38-41) for the purpose of providing a strong attachment between the coil and the mandrel. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Rodriguez et al. with proximal and distal wire coils laser welded to the mandrel portion as taught by Erickson et al. for the purpose of providing a strong attachment between the coil and the mandrel.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDR

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700